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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,333

11/20/2006

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EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

4121

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/557,333	<b>Applicant(s)</b> SING ET AL.	
	<b>Examiner</b> SARAH AL-AWADI	<b>Art Unit</b> 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/30/2006, 04/25/2008 and 07/24/2008</u> .                   | 6) <input type="checkbox"/> Other: _____                          |



***DETAILED ACTION***

***Information Disclosure Statement***

The IDS filed 01/30/2006, 04/25/2008, and 07/24/2008 are acknowledged.

***Response To Remarks***

Applicant's election without traverse of an apparatus group IV claims 24-32 in the reply filed on 03/20/2009 is acknowledged.

Claims 1-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/20/2009.

The examiner has determined that there is no undue search burden required for the species election and so the species election requirement is hereby lifted.

***Priority***

Application 60/478,307 filed 06/12/03 is acknowledged. All claims under consideration were given a priority date of 06/12/2003.

***Specification***

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The attempt to incorporate subject matter into this application by reference to US Patent Applications, 09/621670, 10/007204 10/461587 and United States Patent 6,086,607 is ineffective for establishing a means step because the specification does not distinctly point to where in the provided references each means step is being performed.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite an apparatus without any description or support in the specification of the structural limitations of the apparatus.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...”) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See

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MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to an apparatus with a means for heating, adding reagents, mixing reagents, adding air and drying above freezing point temperature.

**(1) Level of skill and knowledge in the art:**

The level of skill and knowledge in the art is very high.



**(2) *Partial structure:***

The specification does not describe the structural limitations of the apparatus in claims 24-32. Furthermore, there are no drawings that provide details and support of the apparatus claims.

**(3) *Correlation between structure and function:***

No description or drawings are provided in the specification for structural and functional limitations of the apparatus. It is not clear how the apparatus heats things, or adds reagents, mixes reagents, or adds air to the mixture. For example, regarding heating, it is not clear at what temperature this is performed or how it is preformed. Reagents can be heated in a numerous types of ways such as water baths, or hybridization ovens with varying temperatures.

**(4) *Method of making the claimed invention:***

No description is provided how to make the apparatus. The possible structural variations are limitless to any apparatus that can heat, add reagents, mix reagents, add air, and dry above a freezing point temperature. The claim lacks written description because there is no disclosure of a correlation between function and structure of the apparatus. For example, it is not clear how the apparatus in the instant application heats, mixes, or adds reagents. Moreover, the specification lacks sufficient structural examples to encompass the claimed apparatus and does not provide sufficient descriptive support for the limitations of the apparatus. The description requirement of the patent statute requires a description of an invention, not an indication of a result that

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one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-28 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because it is not clear the structural limitations with relation to an apparatus claim, how a means for heating, means for adding a cross-linking agent, means for mixing a clot formation accelerator, and means for adding air are being performed. There is no description in the specification that discloses limitations how the apparatus heats, mixes, and adds air to the solution. For the purposes of examination the examiner broadly and reasonably interprets claim 24 to be that of an

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apparatus that heats solution, mixes, and adds air. Therefore claims 25-28 are also indefinite as they depend on claim 24.

Claim 29 is indefinite because it is not clear the limitations with relation to an apparatus claim exactly how a means for heating gelatin, means for adding a cross-linking agent, means for mixing, and means for drying clot formation accelerator mixture are being performed. There is no description in the specification that discloses limitations how the apparatus heats, mixes, and dries. For the purposes of examination the examiner broadly and reasonably interprets claim 29 to be that of an apparatus that heats solution, mixes, and dries solution.

Claim 30 is indefinite because it is not clear what is meant by means for heating by adding polysaccharide. There are numerous ways which an apparatus can heat a solution, and the phrase "means for heating" is vague and indefinite. Furthermore it is vague and indefinite how adding a polysaccharide to solution is related to heating the solution. Claims 31 and 32 are also rejected as being vague and indefinite as they depend on claim 30. Furthermore, claims 31 and 32 are not further limiting the apparatus of claim 29.

Claim 25 recites the apparatus of claim 24, and wherein said means for dissolving further comprises adding a polysaccharide. There is insufficient antecedent basis for this limitation in the claim because there is no dissolving step in claim 24 to which claim 25 depends upon. Furthermore, claims 26-28 are rejected as having insufficient antecedent basis because they are dependent on claim 25, and they are not further limiting the apparatus.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-27 and 30-32 are rejected under 35 U.S.C. 101.

Claims 25-27 and 30-32 are rejected under 35 U.S.C. 101 because the claims overlap in two different statutory classes of invention. There is both a process step and apparatus in claims 25 and 30. Furthermore, MPEP 2173.05 (p) (II) states that "a single claim which claims both an apparatus and a method step of using the apparatus is indefinite under 35 U.S.C. 112 2nd paragraph, and also rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a process nor a machine, but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-32 are rejected under 35 U.S.C. 102 (b) as being anticipated by Markwardt et al. United States Patent 4,924,764.

It is noted that Applicant has met 112 6<sup>th</sup> paragraph for means plus function and because no support is provided in the specification for means and function and there is improper incorporation by reference, claims 24-32 will be broadly and reasonably interpreted without any functional limitations for the means plus function language.

Claim 24 is broadly interpreted as an apparatus that can heat solution by any means, add reagents, mix reagents, and add air. The fact that granules are being heated, a cross-linking reagent is being added, and a clot formation accelerator is being added are not given any patentable weight for the apparatus claims as they do not impart any additional limitations to the structure of the apparatus. Claims 25-27 are also broadly interpreted as being drawn to the apparatus of claim 24 and are not further limiting.

Reference '764 teaches an apparatus (claim 9 and figure 1) that has a means for mixing solution, a means for heating solution, and a means for adding compressed air to the solution, and adding reagents such as boiled sugar solution. (claim 9)

Claim 28 is interpreted as being drawn to an apparatus that comprises a means for drying any material above a freezing point temperature.

Reference '764 discloses a vacuumizing step to reduce water content through vaporization. (claim 9) Vacuumizing is drying above freezing point temperature as it is reducing the water content (drying) of sugar mass through vaporization.

Claim 29 is broadly and reasonably interpreted as being drawn to an apparatus that has a means for heating, means for adding reagents, a means for mixing solutions, and a means for drying at a temperature above freezing point temperature.

Reference '764 discloses an apparatus that has a means for mixing solution, means for heating, means for adding reagents such as boiled sugar solution, and a means for drying above a freezing point temperature. (Claim 9 and figure 1) The apparatus of reference '764 dries above a freezing point temperature because claim 9 discloses that the vacuumizing reduces water content through vaporization.

Claims 30-32 are broadly and reasonably interpreted as the same apparatus of claim 29 which has a means for heating and are not further limiting. Reference '764 discloses an apparatus that has a means for heating, means for mixing, adding reagents, and drying above a freezing point temperature. (claim 9)

Claims 29-32 are rejected under 35 U.S.C. 102 (b) as being anticipated by Helbig et al. United States Patent 4,502,228.

It is noted that Applicant has met 112 6<sup>th</sup> paragraph for means plus function language, and because no support is provided in the instant specification for means and function and there is improper incorporation by reference, claims 24-32 are broadly and

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reasonably interpreted without any functional limitations for the means plus function language.

Claim 29 is broadly interpreted as an apparatus that can heat solution by any means, add reagents, mix reagents, and drying by any means. The fact that granules are being heated, a cross-linking reagent is being added, and a clot formation accelerator is being added are not given any patentable weight for the apparatus claims as they do not impart any additional limitations to the structure of the apparatus.

Patent '228 describes an apparatus with drying and mixing compartments and a heating chamber. (column 2, lines 44-57) The examiner interprets drying at a temperature above freezing point temperature to include that of drying by any means that does not include freeze drying. Therefore, the instant application is anticipated by the apparatus of '228 in that a heating chamber, drying chamber and mixing chamber are present.

Claims 30-32 are indefinite and vague as discussed supra, and do not impart any additional structural limitations to the apparatus of claim 29. Therefore, for the purpose of examination the Examiner broadly and reasonably interprets claims 30-32 to be the same apparatus as claimed in claim 29 without additional limitations. Patent '228 anticipates the apparatus of the instant claims. Patent '228 teaches an apparatus with drying and mixing compartments and a heating chamber. (column 2, lines 44-57) The examiner interprets drying at a temperature above freezing point temperature to include that of drying by any means that does not include freeze drying. Therefore, the instant

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application is anticipated by the apparatus of '228 in that a heating chamber, drying chamber and mixing chamber are present.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 8:30 am - 5:30 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/  
Examiner, Art Unit 4121

/Patrick J. Nolan/  
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